

FOCUS GROUP QUESTIONS - OMB - 0910-0497

The focus group will cover 3-7 questions (subject to time restraints) related to the recruitment and retention in clinical trials. These questions include:

1. What are the most important patient factors that pose a barrier to recruiting patients for post-approval studies?
 - a. What are the patient factors that increase recruitment success?
 - b. What are the patient factors that decrease recruitment success?
 - c. Are there different patient factors in pre- and post approval studies?
 - i. Do patients care about the science? How do patients perceive the pre-approval study requirements compared with the post approval study requirements?
 - ii. Does this/How does this impact patient recruitment?
What are some strategies that have been successful in overcoming a long term commitment?
 - d. Do these factors vary by the type of site (academic, community, etc.)?
 - e. Is there variation based on geography?
 - f. Are they influenced by socio-economic factors?
 - g. Are there different patient demographic factors affecting recruitment?
 - i. Age
 - ii. Sex
 - iii. Race/ ethnicity
2. Does paying participants for time, travel, etc increase interest in participating?
 - a. What should influence payment level?
 - b. Is there a critical payment level?
 - c. When considering all factors influencing patient participation, at what point are the cumulative benefits of participating in PAS coercion (at worst) or likely to introduce bias (at best)?
 - i. Can this be determined up front, or how can it be detected after the fact?
 - d. If payment isn't a key factor, what is the best incentive for patients to participate?
3. What is the most important factor that motivates patients to stay in a clinical trial?
4. What are some of the patient retention strategies that have been used and what are the pros and cons of these strategies?
5. Do pre- and post- approval studies have different factors that impact retention?
 - a. Logistics (transportation, time off work, relocation)?
 - b. Patient outcome?
 - c. Access to care?
 - d. Access to specialist?
 - e. Payment for follow-up care?
 - f. Assurance of payment for treatment of AEs?
 - g. Insurance payments?
6. Do the retention factors vary depending on the method of follow-up?
 - a. In-person, clinic visits
 - b. Phone follow-up
 - c. Mail or internet follow-up
 - d. Remote monitoring

7. "Non-captive" patients (those with quality of life conditions, e.g., back pain) may be significantly less likely to continue long term follow up compared with "captive" patients (those with life threatening conditions, e.g., cardiac conditions) because they may be more likely to drop out when they get better.
 - a. Since the motivation to participate is different, should this be taken into consideration when arriving at the type/amount of incentive to participate in long term follow up?
 - b. At what amount does an incentive become 'coercive' for each of these groups? Does payment structure, e.g., back loading, potentially improve retention or is it coercive?